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13. ABSTRACT (Maximum 200 words) The purpose of this study was to determine the strength of the relationship between patient height versus vertebral column length and the level of subarachnoid sensory blockade following administration of 15 mg of 0.75% hyperbaric bupivacaine. Patient height has traditionally been used to determine the dose of local anesthetic for patients undergoing spinal anesthesia. It has been proposed that a patient's vertebral column length may be more reliable than patient height when estimating local anesthetic dosages. This study offers sound methodology, an adequate sample size, and the data to support the continued use of patient height to safely estimate the dose of local anesthetic for subarachnoid blockade. This study was conducted at Darnall Army Community Hospital, Fort Hood, Texas. A nonprobability, convenience sample was selected from patients presenting for elective surgical procedures in which subarachnoid blockade was appropriate. The researchers measured the patient's height and vertebral column length to the nearest centimeter. Interrater reliability was established among the researchers. Twenty minutes after the anesthetic was administered, the level of sensory blockade was assessed by a blinded observer using the pinprick method and recorded on the data collection tool. Interrater reliability was established among the four blinded observers. There was a weak, but statistically significant correlation between patient height and the level of sensory blockade. There was no correlation between vertebral column length and the level of sensory blockade. Study findings demonstrated that ASS I and II male subjects achieved an average level of sensory blockade of T6. The generalizability of this finding offers the anesthetist a quick and reliable anesthesia plan. Having a reliable anesthetic plan benefits both the patient and organization by limiting the complications associated with an inadequate or excessively high spinal blockade.			
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VERSUS VERTEBRAL COLUMN LENGTH AND THE LEVEL OF  
SUBARACHNOID SENSORY BLOCKADE PRODUCED USING  
0.75% HYPERBARIC BUPIVACAINE

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Submitted in partial fulfillment

of the requirements for the degree of

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## Abstract

The purpose of this study was to determine the strength of the relationship between patient height versus vertebral column length and the level of subarachnoid sensory blockade following administration of 15 mg of 0.75% hyperbaric bupivacaine. Patient height has traditionally been used to determine the dose of local anesthetic for patients undergoing spinal anesthesia. It has been proposed that a patient's vertebral column length may be more reliable than patient height when estimating local anesthetic dosages. This study offers sound methodology, an adequate sample size, and the data to support the continued use of patient height to safely estimate the dose of local anesthetic for subarachnoid blockade.

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There was a weak, but statistically significant correlation between patient height and the level of sensory blockade. There was no correlation between vertebral column length and the level of sensory blockade. Study findings demonstrated that ASA I and II

male subjects achieved an average level of sensory blockade of T6. The generalizability of this finding offers the anesthetist a quick and reliable anesthesia plan. Having a reliable anesthetic plan benefits both the patient and organization by limiting the complications associated with an inadequate or excessively high spinal blockade.

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The Committee for the  
Protection of Human Subjects

September 15, 1995

**NOTICE OF APPROVAL TO BEGIN RESEARCH**

HSC-SN-95-027 - "Comparison of the Relationship Between Patient Height versus the Vertebral Column Length and the Level of Subarachnoid Sensory Blockade Produced Using 0.75% Bupivacaine"  
P.I.: Bonnie Bequette, MSN Student; Chair - Dr. Levine

**PROVISIONS:** Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consents, etc.

**APPROVED:** At a Convened Meeting

**APPROVAL DATE:** September 15, 1995

**EXPIRATION DATE:** August 31, 1996

**CHAIRPERSON:** Alan C. Swann, M.D. *Alan C. Swann*

Subject to any provisions noted above, you may now begin this research.

**CHANGES** - The P.I. must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. **ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.**

**INFORMED CONSENT** - Informed consent must be obtained by the P.I. or designee using the format and procedures approved by the CPHS. The P.I. must instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document.

**UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS** - The P.I. will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

**RECORDS** - The P.I. will maintain adequate records, including signed consent documents if required, in a manner which ensures confidentiality.

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## CHAPTER I

### Introduction

The goal of regional anesthesia is to block impulse conduction in neural tissue (neural blockade) to render a region of the body insensitive to noxious stimuli (Cousins & Bridenbaugh, 1988). The clinician's ability to deliver an adequate level of neural blockade for the proposed surgical procedure is of utmost importance to the patient. For the patient, adequate sensory blockade translates into an attenuation of the physiologic and psychologic changes associated with surgery. Subarachnoid block (SAB) is a regional anesthetic that is frequently used by anesthetists for the management of the patient during the perioperative period.

It has been suggested that patient variables influence the ultimate level of neural blockade following subarachnoid injection of local anesthetics. In current clinical practice, the patient's height is often used when determining the dose of drug to inject into the subarachnoid space (Norris, 1990). It is clinically acceptable to inject larger doses of an anesthetic in taller patients but to date, few studies have been conducted to support this practice.

Greene (1985) proposed that taller patients with larger and longer spinal columns have lower dermatome levels of neural blockade than shorter patients using the same amount of local anesthetic. This is assuming that the local anesthetic travels a similar longitudinal distance in both types of patients. Taller patients also have a greater volume of cerebrospinal fluid (CSF), which dilutes the concentration of the injected local anesthetic thereby decreasing the effectiveness of the drug. Greene suggested that the

length of the vertebral column rather than patient height may be the more appropriate variable to consider when determining the dose of anesthetic for a subarachnoid block. Therefore, conflicting information in the anesthesia literature suggests a need to further investigate the relationship of the vertebral column length and the resultant level of sensory blockade produced.

#### Statement of the Problem

Patient height is considered an important determinant of the dose of a spinal anesthetic, however, the relationship between body height and the level of sensory anesthesia is not clearly documented. A relationship has been proposed between vertebral column length and the level of subarachnoid sensory blockade (Greene, 1985; Lin et al., 1992). Although little research has been conducted in this area, it is feasible that vertebral column length, an indirect measure of the subarachnoid space (Moore, 1982), may be a better indicator than height in determining the level of sensory blockade achieved.

#### Conceptual Framework

Stienstra and Greene (1991) stated that the distribution of a local anesthetic in the subarachnoid space and the effect of the medication on neural blockade is influenced by 11 factors (see Figure 1). However, for the purposes of this study nine factors will be examined. These nine factors may be grouped into four categories: patient characteristics, technique, CSF characteristics, and characteristics of the anesthetic solution. Each group of factors influences the level of sensory blockade and may also influence the other factors.

Patient characteristics include patient age, height, and vertebral column length. These

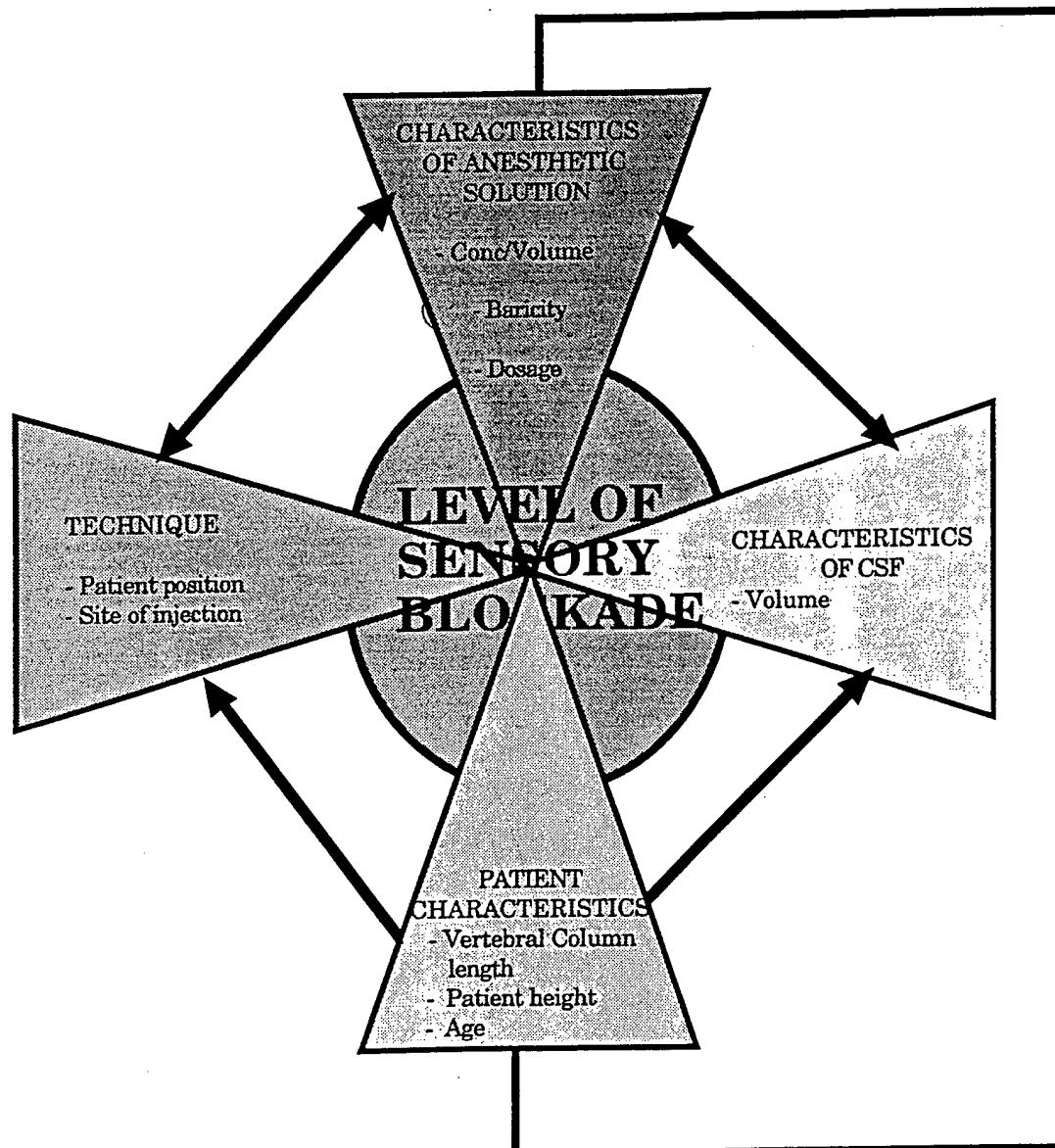


Figure 1. Factors influencing distribution of anesthetic within the subarachnoid space.

characteristics may influence the level of sensory blockade. The patient's height is commonly used to calculate the anesthetic dosage. A larger dose may result in a higher level of sensory blockade. This study will explore the relationship between patient height versus vertebral column length and the level of sensory blockade.

The patient's height may contribute to the volume of cerebrospinal fluid in the subarachnoid space. Theoretically, a taller person has a greater volume of CSF versus a shorter person. This greater volume of CSF dilutes the anesthetic solution resulting in a lower level of sensory blockade (Greene, 1985).

A patient's age influences the level of sensory blockade, contributes to the volume of CSF in the subarachnoid space, and modifies the anesthetic solution's effects. Patients greater than 50 years of age experience a level of sensory blockade two to three dermatome levels higher than younger patients. This increased level of blockade is believed to be associated with a decreased number of nerve fibers and the effects of demyelination (Pitkanen, Haapaniemi, Tuominen, & Rosenberg, 1984; Veering, Burm, van Kleef, Hennis, & Spierdijk, 1987). Additionally, the CSF volume decreases with age, which results in a greater spread of anesthetic solution and a higher level of sensory blockade. Due to the above factors, older patients require decreased anesthetic dosages for subarachnoid blockade.

The relationship between vertebral column length and subarachnoid sensory blockade has not been extensively studied. Hartwell, Aglio, Hauch, and Datta (1991) reported a weak, statistically significant correlation ( $r = 0.32$ ,  $p = 0.0250$ ) between vertebral column length and level of sensory blockade. Whereas, Huffnagle et al. (1994) and Norris (1990)

reported no correlation ( $r = 0.1673$  and  $r = 0.0245$  respectively) between vertebral column length and the level of sensory blockade. Also, Perez-Tamayo, Zetina-Velez, and Aldrete (1977) reported no correlation between vertebral column length (sitting height) and level of sensory blockade, but provided no statistical data to support this conclusion.

The patient's characteristics also influence the anesthesia provider's choice of technique. For instance, the provider who is concerned about the severity of ligament calcification in an elderly patient may perform a subarachnoid block using a paravertebral versus midline approach. Another example is a patient presenting for a subarachnoid block who has developed a localized lesion at the L3-4 interspace. This is an indication for the anesthesia provider to select another site for injection or to choose another anesthetic technique. By considering patient characteristics, the anesthesia provider selects an appropriate technique and tailors the local anesthetic concentration, volume, and dose to achieve an adequate level of sensory blockade.

The selection of the local anesthetic solution and the anesthetic technique are both influenced by the patient characteristics. These characteristics also guide the selection of the appropriate medication to include dosage, volume, concentration, and baricity. The technique (patient position and site of injection) is selected based on patient characteristics and characteristics of the anesthetic solution.

Figure 1 illustrates that characteristics of the anesthetic solution and technique of injection are related such that one cannot be discussed without the other. The characteristics of the anesthetic solution include concentration/volume, dosage, and baricity. For example, the surgical procedure and related patient position determine the

type of local anesthetic to be used. The classification of the solution for spinal anesthesia depends on whether it is heavier (hyperbaric), equal to (isobaric), or lighter than (hypobaric) CSF. Hyperbaric solutions gravitate to dependent areas, isobaric solutions remain localized at the site of injection, and hypobaric solutions float to the nondependent areas.

The patient position can influence the distribution of local anesthetics in the CSF. For instance, the patient undergoing a hemorrhoidectomy may be positioned in the jackknife or high lithotomy position. When using a hypobaric solution, the spinal is usually placed with the patient in the jackknife position. This allows a hypobaric solution to gravitate toward the desired surgical site (S2-4 dermatomes). For the patient undergoing a hemorrhoidectomy in the lithotomy position, a hyperbaric solution is usually injected with the patient in the sitting position. This allows the hyperbaric solution to gravitate toward the desired surgical site prior to placement in the lithotomy position (Covino & Lambert, 1992).

The characteristics of the anesthetic solution and volume of CSF are closely related. Patients with a greater volume of CSF may require more anesthetic to achieve an appropriate level of sensory blockade. On the other hand, patients with increased intra-abdominal pressure have decreased volumes of CSF. Therefore, less anesthetic solution may be required in term parturients, patients with ascites and in patients with intra-abdominal tumors to achieve the appropriate level of sensory blockade (Greene, 1985).

The level of sensory blockade achieved is directly related to the characteristics of the

anesthetic solution, which are concentration/volume and dosage of the anesthetic solution. The larger the dose (milligrams) of a local anesthetic injected into the subarachnoid space, the higher the resultant level of sensory and neural blockade. By altering the concentration (0.25% versus 0.75%) of local anesthetic, the anesthesia provider can modify the type of neural blockade achieved (Greene, 1985).

By considering the nine factors presented in Figure 1, the anesthesia provider estimates the local anesthetic dose requirements for spinal anesthesia. The preoperative interview determines the patient's health status, the patient's preferences, and appropriate anesthetic plan (general anesthesia versus regional anesthesia). The anesthesia care plan is individualized or tailored to the patient and adjustments are made to achieve an appropriate level and duration of blockade, based on the proposed surgical procedure.

#### Purpose of the Study

The purpose of this study was to determine the strength of the relationship between patient height versus vertebral column length and the level of sensory blockade produced following subarachnoid administration of 15 milligrams (mg)/2 milliliters (ml) of 0.75% hyperbaric bupivacaine in selected surgical patients undergoing spinal anesthesia.

#### Research Question

What is the correlation between patient height versus the vertebral column length and the level of subarachnoid sensory blockade produced when using 15 mg of 0.75% hyperbaric bupivacaine?

#### Definition of Terms

ASA physical status classification. A five category classification developed by the

American Society of Anesthesiologists to rank patients according to surgical risk.

ASA I. The patient has no physical, biological, or psychological pathology.

ASA II. The patient has mild to moderate controlled systemic disturbances caused by either the condition to be treated surgically or by other pathophysiologic processes.

Blockade. The loss of sensation to a specific area of the body following administration of a local anesthetic agent. For this study the maximum level of sensory blockade will be determined by patient response to sharp pinprick 20 minutes after injection of the spinal anesthetic.

Introducer. A large gauge needle through which the spinal needle is inserted. It assists in the penetration of the superficial tissue and subarachnoid space and also provides support for the spinal needle.

Level of subarachnoid sensory blockade. The ultimate level of pain (sensory) block achieved following spinal anesthetic administration. Twenty minutes after the anesthetic administration the level of sensory blockade will be assessed using the pinprick method. The height of the sensory blockade will be determined and recorded in dermatome levels at the point which the patient can sense and verbalize a change in the sensation (sharp versus dull) elicited by a 22 gauge needle in the midaxillary line.

Patient height. A measurement in centimeters (cm) of the patient in the standing position.

Site of injection. The intervertebral space, L3-4 or L4-5, where the needle will be introduced to inject the anesthetic agent.

Subarachnoid block (SAB). The injection of a local anesthetic solution into the

subarachnoid space in sufficient dosage to inhibit conduction of sensory, motor, and autonomic fibers.

Vertebral column length. For the purposes of this study, the vertebral column length, an indirect measure of the subarachnoid space, is defined as the distance from the base of the skull to S2 with subjects in the standing position, measured to the nearest centimeter.

#### Assumptions

1. Cerebral spinal fluid (circulation, pressure, density, and composition) varies insignificantly among patients in the general population and therefore does not affect the distribution of anesthesia in the subarachnoid space.
2. The pharmacokinetics of the anesthetic drug will allow for similar distribution in the subarachnoid space among the study sample.
3. The effect of temperature on the baricity of the solution in the cerebral spinal fluid (20°C versus 37°C body temperature) will not be clinically significant because temperature of the solution will equilibrate within one to three minutes. Therefore, the anesthetic solution used will be injected at ambient temperature.
4. Turbulence and speed of injection can be ruled out as factors having an effect on the spread of local anesthetic solution (Becker, Callesen, Thage, Bertelsen, & Christiansen, 1993).
5. According to Becker et al. (1993) there is an insignificant relationship between the maximum level of sensory blockade and the lumbar location (L2-3, L3-4, or L4-5) at which the local anesthetic is injected.

### Significance of the Problem

This study determined the strength of the relationship between patient height versus the vertebral column length and the level of subarachnoid sensory blockade produced following subarachnoid administration of 15 mg of 0.75% hyperbaric bupivacaine. The determination of whether patient height or vertebral column length influences the level of subarachnoid sensory blockade achieved may allow practitioners to more accurately determine required dosages and estimate the level of sensory blockade. This would thereby limit complications from an excessively high or inadequate level of sensory blockade. An excessively high level of spinal blockade compromises the patient's respiratory and cardiovascular status and may necessitate the induction of general anesthesia. An inadequate level of sensory blockade is an uncomfortable experience requiring the use of additional medications to provide anesthesia and analgesia and may necessitate the induction of general anesthesia. With predictable levels of sensory blockade, patients could have a more pleasant surgical experience, diminished pain response, and an earlier hospital discharge. Additionally, for the patient who desires to remain awake, regional anesthesia may provide an increased sense of control (Cousins & Bridenbaugh, 1988).

If the level of sensory blockade could be more accurately determined, it would optimize the use of intraoperative and perioperative services. For the health care organization, the ability of the anesthesia provider to maximally control the level of sensory blockade results in improved use of operating room resources by limiting surgical delays attributed to an inadequate or excessively high spinal block.

Limitations

1. The results of this study can only be generalized to subarachnoid techniques using a pencil point spinal needle with patients in the sitting position.
2. The results of this study were limited to those patients whose surgery was performed in the supine position.
3. Generalization of the findings can only be made to patients receiving 15 mg of 0.75% hyperbaric bupivacaine.
4. The results can only be generalized to patients who were similar to the sample in the categories of age, weight, anatomic characteristics of the vertebral column, lack of neurologic disease, nonparturient status, and general physical health.

Summary

A subarachnoid block is frequently used to provide anesthesia for surgical patients. Currently, patient height is often used to determine anesthetic dosage, although there is no clearly documented relationship between patient height and the level of sensory blockade. Greene (1985) and Hartwell et al. (1991) suggested that vertebral column length may be a more accurate determinant of the level of subarachnoid blockade. The determination of whether patient height or vertebral column length influences the level of subarachnoid sensory blockade achieved would allow practitioners to accurately determine required dosages and estimate the level of sensory blockade. This would thereby limit excessively high and/or inadequate spinal blocks and their resultant complications. This could ultimately benefit both patient and clinician through improved perioperative outcomes and use of operating room resources.

Research efforts have clearly documented the contributions of age, patient positioning, volume of CSF, baricity, dosage, and concentration/volume of anesthetic solution on the level of sensory blockade produced during subarachnoid blockade. Although a relationship has been proposed between vertebral column length and the level of sensory blockade (Greene, 1985; Hartwell et al., 1991), little research has been conducted in this area. Currently, in a review of the literature, few studies have explored the relationship between patient height versus vertebral column length and the level of subarachnoid blockade (Hartwell et al, 1991; Huffnagle et al., 1994; Norris, 1990).

## CHAPTER II

### Review of Related Literature

Current research indicates that eleven factors are clinically important in influencing the distribution of local anesthetics in the subarachnoid space (Stienstra & Greene, 1991). For the purposes of this study, the following discussion was based on these nine factors: patient age, patient height, anatomic characteristics of the vertebral column, site of injection, patient positioning, volume of CSF, baricity, dosage, and volume/concentration of the anesthetic solution.

#### Patient Age

Discrepancies exist between the few studies concerning the effect of age on the spread of sensory blockade. Some studies found increased patient age to be associated with statistically significant higher levels of sensory blockade (Cameron, Arnold, Ghoris, & Jamieson, 1981; Pitkanen et al., 1984). In other studies the relationship between age and level of sensory blockade was not found to be clinically significant (Norris, 1990; Tuominen, Pitkanen, Doepel, & Rosenberg, 1987; Veering et al., 1987).

Cameron et al. (1981) studied the effect of age on the level of sensory blockade when using 4 ml of isobaric 0.5% bupivacaine injected at the L2-3 interspace. A moderate, statistically significant ( $r = 0.5$ ,  $p = 0.003$ ) correlation between increasing age and level of sensory blockade was found in 33 patients ranging from 37 to 97 years of age. Similarly, Pitkanen et al. (1984) studied the effects of age on the level of sensory blockade using 3 ml of 0.5% isobaric bupivacaine in 124 patients whose ages ranged from 15 to 92 years.

Only small differences were observed between the mean maximum spread of pinprick analgesia in the different age groups because the ranges of spread were considerable. However, statistical evidence of higher spinal blockade in the older age groups was obtained, as was a weak correlation ( $r = 0.227$ ,  $p < 0.05$ ) between age and spread of analgesia. Although a mean difference in the pinprick analgesia of about two to three spinal segments was seen throughout the induction period between younger (< 50 years) and older patients, this difference was statistically significant only at five and 60 minutes ( $p < 0.01$ ), when individual groups were combined. Therefore, because of the large variation between individuals, no statistical significance could be established between individual groups.

In contrast, Tuominen et al. (1987) found no influence of age on the distribution of sensory analgesia following subarachnoid injection of 15 mg of hyperbaric tetracaine in 60 patients ranging from 17 to 82 years of age. Veering et al. (1987) studied the effects of 15 mg of 0.5% isobaric bupivacaine in 29 patients ranging from 20 to 87 years of age. They reported that older patients experienced a higher maximum level of analgesia than younger patients ( $r = 0.33$ ,  $p = 0.07$ ). Similarly, Norris (1990) found a statistically nonsignificant ( $r = 0.0316$ ,  $p > 0.05$ ) trend toward increasing level of anesthesia with increasing age when using 15 mg of hyperbaric 0.75% bupivacaine with 0.15 mg of morphine. When using hyperbaric drugs, the effects of baricity may predominate over those of age. In these studies, the effect of age was small and of little importance in normal clinical circumstances (Greene, 1985; Moore, 1982).

In summary, although there was a tendency for greater spread of spinal analgesia with

isobaric bupivacaine in older age groups, as demonstrated by Pitkanen et al. (1984) and Cameron et al. (1981), these findings were weakly correlated with age. The clinical importance of these findings is questionable because of the large individual variation of analgesic spread in all age groups. It is concluded that despite certain age-related statistical differences in spinal block with isobaric bupivacaine, individual predictability still remains poor and the clinical relevance of the effect of age on the maximal height of analgesia is inconclusive.

#### Patient Height

There are conflicting reports regarding the effect of height on the spread of subarachnoid hyperbaric anesthesia with bupivacaine. Despite a 13 cm difference in height among males and nonparturient females, Brown, Wildsmith, Covino, and Scott (1980) reported no significant difference in the level of sensory blockade achieved ( $n = 60$ ). Norris (1988) found no significant difference ( $r = 0.21$ ;  $p = 0.15$ ) in the level of sensory blockade despite a 29 cm range in height when 12 mg of 0.75% hyperbaric bupivacaine was administered to a sample of 50 term parturients. In a more recent study, Norris (1990) used 15 mg of 0.75% hyperbaric bupivacaine with 0.15 mg of morphine and found no correlation between patient height and level of sensory blockade.

Huffnagle et al. (1994), however, found a weak, statistically significant correlation between height and subarachnoid spread ( $r = 0.387$ ,  $p < 0.05$ ) in a sample of 44 postpartum ASA I and II women using 75 mg of 5% hyperbaric lidocaine. The sample size is too small to change clinical practice based on the results of this study. In a retrospective study of 435 patients, Moore (1982) described a significant relationship

( $p < 0.005$ ) between height and spread of blockade following administration of either 7.5 mg of hyperbaric bupivacaine or 12 mg of hyperbaric tetracaine, but presented no data to support this conclusion. Also, no power analysis or correlation ( $r$ ) value was provided. Attygalle (1985) studied the effect of 10 mg of 0.5% hyperbaric cinchocaine in different volumes (6 ml and 8 ml) in 83 subjects. He also reported a weak, negative correlation ( $r = -0.2$ ,  $p < 0.001$ ) between patient height and dermatome level.

To date, most researchers have used small sample sizes, which at best constitute pilot studies (Brown et al., 1980; Huffnagle et al., 1994; Norris, 1988, 1990). Inconsistencies exist in the literature concerning the effect of patient height on the level of sensory blockade following administration of local anesthetics in the subarachnoid space.

#### Anatomical Characteristics of the Vertebral Column

Early reviews by Greene (1985) indicated that no systematic studies were done involving vertebral column length, patient height and the level of sensory blockade. Greene stated that the diameter of the spinal cord is greater and the cauda equina is longer in tall patients, which suggests that taller patients require more anesthetic. Additionally, Hartwell et al. (1991) administered 12 mg of 0.75% hyperbaric bupivacaine to 50 postpartum subjects. They determined that measuring the vertebral column from C7 to the iliac crest ( $r = 0.32$ ,  $p = 0.025$ ) and C7 to the sacral hiatus ( $r = 0.38$ ,  $p = 0.006$ ) provided a more accurate approach to dose selection than patient height in determining the level of sensory blockade. Also, Hartwell et al. stated that because kyphosis normally occurs at T6, hyperbaric solutions produce a block to the T4-6 region. Lordotic conditions were shown to produce a decreased cephalad spread of spinal anesthesia,

possibly due to exaggerated lumbar lordosis and diminished thoracic kyphosis. As with other studies, the sample size was small and it would be beneficial to replicate this study with a larger sample size.

An earlier study by Perez-Tamayo et al. (1977) examined the relationship between sitting height and the resultant level of sensory blockade in 40 patients scheduled for elective bilateral salpingectomies. The subjects were divided into two groups: one group received 5 mg of hyperbaric tetracaine while the other received 8 mg. Perez-Tamayo et al. reported no correlation between sitting height and the level of sensory blockade.

Abnormal curvature of the spinal column such as lordosis and kyphosis affect the spread of spinal anesthesia (Greene, 1985). Smith (1968) measured both the dose of hyperbaric tetracaine and flexion and/or extension of the knees. Using a sample size of 100 patients (divided into four groups of 25 each), he determined that the height of sensory blockade could be 1.5 to 2.0 dermatomes higher by altering the curvature of the lumbar spine. He accomplished this by having patients lay supine with knees flexed for two to three minutes following the administration of spinal anesthesia. Inconsistencies exist in the literature concerning the effect of the anatomical characteristics of the vertebral column and the resultant level of sensory blockade (Hartwell et al., 1991; Perez-Tamayo et al., 1977; Smith, 1968). Further research should be conducted to examine the relationship between the vertebral column characteristics and the level of sensory blockade.

#### Site of Injection

The relationship between the site of injection of the local anesthetic and the

subsequent level of sensory blockade produced varies widely. According to Greene (1985), the volume of CSF per spinal cord segment is less above L2 than below, and injection of the local anesthetic into the L2-3 interspace results in a more cephalad shift in the level of sensory blockade. Sundnes, Vaagenes, Skretting, Lind, and Edstrom (1982) conducted a study using different volumes of 0.5% hyperbaric bupivacaine to determine if there was a difference in the cephalad spread of analgesia. An unanticipated finding showed no difference in the maximum level of analgesia obtained whether the L2-3 or L3-4 interspace was used. However, the researchers stated that the level of injection used was not randomly determined and the sample size of 30 subjects was small.

Becker et al. (1993) concluded that the maximum level of sensory analgesia was one segment higher when the anesthetic was injected into the L2-3 interspace rather than the L4-5 interspace, using 3 ml of 0.5% isobaric bupivacaine. However, these findings were considered to be statistically ( $p = 0.123$ ) and clinically nonsignificant. The study contained a small sample size of 20 subjects divided into two groups. A power analysis was not discussed, but the researchers did estimate the risk of a type-2 error between 10% and 20%. Tuominen, Taivainen, and Rosenberg (1989) compared the injection of 3 ml of 0.5% isobaric bupivacaine at the L2-3 with the L4-5 interspace using 40 subjects divided into two groups and found a statistically significant ( $p < 0.001$ ) difference of four spinal segments in the maximum level of sensory analgesia. The researchers assumed that the anatomy of the lumbar region may have played an important role in the spread of isobaric bupivacaine in the CSF.

In contrast, Olson et al. (1990) used a sample size of 40 subjects divided into two

groups and found no statistically significant ( $p = 0.46$ ) difference in the level of sensory analgesia whether 4 ml of 0.5% isobaric bupivacaine was injected at the L2-3 or L4-5 interspace. The maximal extent of analgesia was 0.5 spinal segments higher when injection occurred at the L2-3 interspace.

The general consensus is that the site of injection below the second lumbar vertebra is clinically insignificant in determining the level of analgesia. Studies examining the relationship between the site of injection and the subsequent level of sensory blockade using hyperbaric bupivacaine could not be found.

#### Patient Positioning

According to Stienstra and Greene (1991), patient positioning after injection of a hypobaric or hyperbaric local anesthetic is one of the most important determinants of distribution in the subarachnoid space. Greene (1985) stated that distribution of the local anesthetic was strongly influenced by patient positioning during and after injection of the solution.

McClure, Brown, and Wildsmith (1982) demonstrated the influence of patient positioning on the spread of anesthesia by injecting patients with isobaric solutions in various positions. In one group, patients were maintained in the sitting position for two minutes after injection of an isobaric solution, and then placed in the supine position. Another group of patients were injected while in the lateral decubitus position and were immediately turned to the supine horizontal position. Patients maintained in the sitting position achieved a significantly lower level of blockade than those in the lateral decubitus position. Kalso, Tuominen and Rosenberg (1982) also found significant variation in the

spread of sensory blockade related to patient position when 3 ml of 0.5% isobaric bupivacaine was injected. In a sample of 40 patients, the spread of sensory blockade was significantly greater in those who sat for 2.5 minutes compared to those who were immediately placed in the supine position after injection. Thus, patient positioning after injection of local anesthetic is important in determining the level of sensory blockade and is of great importance when providing spinal anesthesia to patients.

#### Volume of Cerebral Spinal Fluid

The composition (Greene, 1985; Kalso et al., 1982), circulation (Grundy, 1960), and pressure (Dubelman & Forbes, 1979; Greene, 1985) of CSF appear to have no significant effect on the level of sensory blockade. However, Greene (1985) and Veering et al. (1987) noted the importance of CSF volume on the level of sensory blockade. They indicated that a higher level of sensory blockade occurred when a given volume of spinal anesthetic solution was distributed in subjects with a decreased CSF volume. For example, Veering et al. (1987) found that the volume of CSF was reduced in elderly patients. The resultant higher concentration of the spinal anesthetic solution in the CSF contributed to a faster and higher level of sensory and motor blockade.

An increase in intra-abdominal pressure causes engorgement of epidural veins in the lumbar and lower thoracic areas, which significantly decreases the volume of CSF (Greene, 1985). This is most clinically evident in term parturients, and in patients with ascites or large intra-abdominal masses. The resultant level of sensory blockade is greater than would be achieved if the same volume of spinal anesthetic solution was administered in patients with no increase in intra-abdominal pressure.

Greene (1985) also noted the importance of CSF on the spread of sensory anesthesia. He indicated that it is logical to assume that there will be a greater dilution of the local anesthetic and therefore less cephalad spread when the volume of CSF is greater in a group of subjects. The length of the cauda equina and resultant volume of CSF below the termination of the spinal cord is greater in tall subjects. There is also a larger volume of CSF above the termination of the spinal cord. This suggests that a local anesthetic would be more dilute. Therefore, in taller subjects the resultant level of sensory blockade may be lower than that of shorter patients.

In conclusion, decreased volumes of CSF result in higher levels of sensory blockade following spinal anesthesia. Conversely, it is postulated that greater volumes dilute the local anesthetic, which results in a lower level of sensory blockade. Thus, except in certain situations such as pregnancy, obesity and aging, the volume of CSF is considered a less important determinant of subarachnoid distribution of a local anesthetic solution.

#### Baricity

The baricity of the anesthetic solution is the ratio of the density of the solution to the density of CSF. According to Brown et al. (1980), baricity is a factor that influences the spread of an anesthetic in the subarachnoid space. The classification of the solution for spinal anesthesia depends on whether it is heavier than (hyperbaric), equal to (isobaric), or lighter than (hypobaric) CSF. The distribution of hyperbaric and hypobaric solutions in the CSF is dependent upon the effects of gravity, which can be influenced by the position of the patient. Brown et al. concluded that the mean spread of analgesia with a hyperbaric solution was five spinal segments higher than injection of the same anesthetic using an

isobaric or hypobaric solution.

Moller, Fernandes, and Edstrom (1984) administered different densities of 4 ml of 0.5% bupivacaine to 30 subjects (divided into three treatment groups) to determine if density had an effect on the subarachnoid spread of analgesia. They concluded that the maximum level of sensory blockade was significantly higher ( $p < 0.05$ ) by three to four spinal segments with the hyperbaric solution, and may also be related to the curvature of the spinal column. The patients were in the lateral position and the tilt of the hips was believed to have influenced the solution to spread cephalad.

Chambers, Edstrom, and Scott (1981) studied the cephalad spread of 15 mg of 0.5% bupivacaine with different baricities and demonstrated that hyperbaric bupivacaine produced significantly higher blocks ( $p < 0.05$ ) compared to the isobaric solution. It is important to note that no power analysis was discussed and the sample consisted of 30 patients divided into three groups. Therefore, this research should at best be considered a pilot study.

The baricity of the anesthetic solution, patient position, and the effects of gravity are important factors influencing the movement of drug in the curvatures of the spine and the resultant level of sensory blockade. Previous research suggested that hyperbaric solutions produced a higher level of sensory blockade than isobaric and hypobaric solutions (Brown et al., 1980; Chambers et al., 1981; Moller et al., 1984). However, as with other investigations evaluating important factors in administering spinal anesthesia, the sample sizes used were small and a power analysis was not presented.

### Dosage, Volume/Concentration of the Anesthetic Solution

Dosage, and volume/concentration of the anesthetic solution share an inseparable relationship because dosage is the product of volume and concentration (Stienstra & Greene, 1991). Dosage and volume/concentration effect the resultant spread of sensory blockade to varying degrees.

When evaluating the significance of the volume to determine the spread of sensory blockade, Sundnes et al. (1982) compared 1.5, 2.0 and 3.0 ml volumes of 0.5% hyperbaric bupivacaine. These researchers concluded that both cephalad spread and duration of block were associated with volume ( $p < 0.05$ ). When designing the study, Sundnes et al. failed to account for the increased dosage of medication that was given and the resultant increase in volume of solution. It is unclear to the reader whether patients received the same dose of 7.5 mg of 0.5% bupivacaine in varying volumes of 1.5, 2.0, and 3.0 ml versus 7.5 mg/1.5 ml, 10 mg/2.0 ml, or 15 mg/3.0 ml. Because this crucial factor was not addressed, one cannot determine whether increased dosage or increased volume was responsible for the increase in cephalad spread of sensory blockade. Another weakness of this study was the small sample size of 29 subjects. According to Cohen (1992), for a moderate effect size with a power of 0.8 and an alpha of 0.05 a sample of 64 subjects was required to answer the research question.

Studies have also been designed to isolate the contribution of each of the interrelated factors of dose and volume/concentration. With a sample of 60 male patients undergoing transurethral surgery, Sheskey et al. (1983) isolated the dosage component by administering different doses (10, 15, and 20 mg) of 0.5% or 0.75% isobaric bupivacaine

in different volumes (1.3, 2.0, 2.7, 3.0 and 4.0 ml). The results indicated that dosage rather than volume was the most important factor with regard to onset of action, duration of anesthesia at the T10 level, and cephalad spread. Again, a weakness of this study was the small sample size. The study had 60 subjects divided equally into six groups. Although this study demonstrated that dosage of local anesthetic was the most crucial factor influencing the sensory spread of analgesia, additional research with larger sample sizes is needed to support these findings.

Van Zundert and De Wolf (1988) corroborated the results of Sheskey et al. (1983) in a study of 50 subjects who received a subarachnoid injection of 12.5 mg bupivacaine in a volume of either 2.5 or 10 ml. The maximum levels of sensory blockade were similar in each group, thus it would appear that blockade level is related to dose and not volume.

The preceding investigations used a bupivacaine solution. Two of the solutions were isobaric and one was hyperbaric. The literature supports that volume may affect subarachnoid distribution, but dosage is the most important factor. Additional research should be conducted in this area before definitive conclusions can be made.

### Summary

The effects of patient age, height, anatomic characteristics of the vertebral column, site of injection, patient positioning, volume of CSF, and baricity, dosage and volume/concentration of the anesthetic solution are important factors that effect the distribution of the anesthetic solution in the subarachnoid space. In addition, research supports the clinical importance of baricity, position, and dosage (McClure et al., 1982) on a set volume of a hyperbaric anesthetic solution injected into the subarachnoid space and

the level of sensory blockade produced. Research findings vary regarding the importance of the site of injection and the level of sensory blockade produced (Becker et al., 1993; Olsen et al., 1990; Kalso et al., 1982).

To date, few studies (Hartwell et al., 1991; Huffnagle et al., 1994; Norris, 1990; Perez-Tamayo et al., 1977) have explored the relationship between patient height versus vertebral column length and the level of subarachnoid sensory blockade achieved. By controlling for the factors listed in the previous paragraph, this study examined the relationship between patient height versus vertebral column length and the level of subarachnoid sensory blockade produced using 0.75% hyperbaric bupivacaine.

## CHAPTER III

### Methodology

The purpose of this study was to determine the strength of the relationship between patient height versus vertebral column length and the level of sensory blockade produced following administration of 15 mg of 0.75% hyperbaric bupivacaine. This study consisted of a nonexperimental, prospective, correlational design. The independent variables of patient height and vertebral column length were not subject to manipulation by the investigators. The population, sample, setting, instrumentation, procedure for data collection, protection of human subjects, study design, and proposed data analysis are described in this chapter.

#### Population, Sample and Setting

##### Population

This study was conducted at Darnall Army Community Hospital, located in Central Texas. Military health care beneficiaries comprised the study population.

Sample. A nonprobability, convenience sample was drawn from a population of patients undergoing elective surgical procedures when a subarachnoid block was appropriate and approved by the surgeon, patient, and anesthesia care provider. The patient possessed the ability and willingness to cooperate after an explanation of the study protocol.

##### Inclusion criteria:

1. ASA I or ASA II
2. Male or female

3. English-speaking
4. 18 to 60 years of age
5. Height between 5'2" (157 cm) and 6'4" (193 cm)
6. Nonemergent procedures
7. Surgical procedures with an incision that did not extend above the T10 dermatome.

The inclusion criteria were established to control for extraneous variables. ASA classifications I and II were selected as representative of a healthy population, to limit confounding the results by subjects' concomitant disease process(es). Both male and female subjects were recruited to provide a representative sample of the population under study.

Only English-speaking subjects were recruited to facilitate accurate communication in acquiring informed consent and the patient's report of sensation during data collection. To avoid the potential influence of physiological and developmental characteristics associated with extremes of age, neither the very young (less than 18 years) or the very old (greater than 60 years) were included in the study. Selection of a height range of 5'2" to 6'4" encompasses 98% of the male population and 83% of the female population (U.S. Bureau of the Census, 1992). The nature of emergency procedures may prohibit the ability to acquire informed consent and the study results may be influenced by the emergency medical condition. Therefore, emergent procedures were not included in this study. In order to decrease the risk of respiratory compromise and a possible inadequate level of analgesia, only surgical procedures with an incision site not extending above the

T10 dermatome were included in the study.

Exclusion criteria:

1. Gravid females up to six weeks postpartum
2. Obese patients (body mass index [BMI] greater than 35)
3. History of neurologic disease
4. Vertebral column abnormalities
5. Allergy to local anesthetics
6. Patient refusal
7. Subjects who increase their intra-abdominal pressure by coughing, sneezing, or

straining within the first 20 minutes after injection will be removed from the study.

The exclusion criteria were selected to control for factors that might skew study results. Pregnancy, including the first six weeks postpartum, is associated with hormonal and physiologic changes that alter the pharmacodynamics and pharmacokinetics of local anesthetics. Increased intra-abdominal pressure associated with obesity, coughing, straining, and sneezing may influence the cephalad spread of local anesthetics. Relative contraindications to regional anesthesia include patients with vertebral column abnormalities and/or a history of neurological disease. Patient refusal and allergies to local anesthetics are absolute contraindications to regional anesthesia.

Sample Size.

There is little research available concerning the variables of interest. When little or no previous research exists, Cohen (1992) recommends using a moderate effect size (0.3) in sample size calculations. With a power of 0.8, a significance level of 0.05, and a moderate

effect size, a sample size of 85 subjects was needed.

#### Instrumentation

Patient height was measured during the preoperative interview to the nearest centimeter. Subjects stood barefoot against a wall-mounted, standardized tape measure. Vertebral column length was measured to the nearest centimeter with subjects in the standing position using a flexible cloth, nonstretchable measuring tape. The length of the vertebral column was measured from the atlanto-occipital joint to the S2 vertebra (Moore, 1992).

Twenty minutes after the anesthetic was administered, the sensory level of blockade was assessed using the pinprick method (Morgan & Mikhail, 1996). The subject was asked to identify sensory changes to needle stimulation. The height of the block was the point at which the subject sensed and verbalized a change in the quality (sharp versus dull) of the sensation produced by a 22 gauge needle along the midaxillary line. The anatomic location of the sensory block was described and documented using a dermatome chart (Cousins & Bridenbaugh, 1988).

#### Procedure for Data Collection

The data collection tool (see Appendix A) was used to collect the following data: hospital number, age, gender, ethnicity, height, weight, vertebral column length, ASA classification, surgical procedure, dermatome level obtained 20 minutes after injection of the SAB, site of injection, and the amount of midazolam administered. With the exception of patient height and vertebral column length, data collection was conducted in the operating room with the subject on a horizontal surgical bed prior to and during the

surgical procedure.

Chambers et al. (1981) observed a plateau of sensory blockade occurring between 15 and 20 minutes after injection of a local anesthetic in the subarachnoid space. A later study of time-courses of zones of sensory blockade with hyperbaric bupivacaine demonstrated that maximal dermatomal height reached a plateau after 15 minutes (Brull & Greene, 1989). In light of this information, data collection continued over 20 minutes to ensure a maximum level of sensory blockade.

#### Protection of Human Subjects

The study proposal was reviewed and approved by the Institutional Review Boards of Brooke Army Medical Center and the University of Texas-Houston Health Science Center prior to data collection. During the consent procedure, the subjects were assured that confidentiality would be maintained and they could withdraw from the study at any time without jeopardizing their care. Each subject was offered a copy of the signed consent form (see Appendix B).

Consent was obtained during the preoperative interview. The potential risks and complications associated with spinal anesthesia were explained to each subject. To ensure privacy, subjects' names and social security numbers were kept confidential and not used in this study. They were assured that the findings would be presented as group data. No subject was identifiable from reported findings.

#### Technique

In order to standardize the procedure, all investigators used the following specific subarachnoid block technique adapted from Covino and Lambert (1992).

1. Subjects were premedicated with up to 0.1 milligram per kilogram (mg/kg) body weight of intravenous midazolam during the preoperative period for anxiolysis. A fluid bolus of 10 milliliters per kilogram body weight of intravenous lactated Ringer's solution was administered prior to the subarachnoid block.
2. Subjects were transported to the operating room and placed in the sitting position on a horizontal operating bed with their feet supported by a stool. Standard monitors (EKG, pulse oximeter, temperature monitor, blood pressure cuff, precordial stethoscope) and other special monitors as appropriate to the subject's physical status were applied. Baseline blood pressure, heart rate, oxygen saturation, and respiratory rate were recorded. Oxygen at two to six liters per minute was administered via face mask. An assistant provided positioning support to ensure patient safety and correct anatomic alignment throughout the administration of the subarachnoid block.
3. The site for the subarachnoid injection was identified via palpation of the vertebral spinous processes and the iliac crests. An imaginary line between the iliac crests intersects the L4 vertebra and was the landmark for locating the L3-4 and L4-5 interspaces.
4. A standard subarachnoid block kit was used for the subarachnoid block.
5. The skin was prepared with an appropriate antiseptic solution using sterile technique and 1% lidocaine was used to produce an intradermal wheal at the L3-4 or L4-5 interspace to reduce patient discomfort during insertion of the introducer needle.
6. The introducer was advanced to the ligamentum flavum using a midline approach between the L3-4 or L4-5 interspace. A 25 gauge Whitacre spinal needle was guided into the subarachnoid space through the introducer. Proper placement was ensured by the

return of CSF.

7. The needle was stabilized by bracing the back of the researcher's nondominant hand against the subject's back holding the hub with the thumb and index finger. This prevented either withdrawal or advancement of the spinal needle during manipulation and injection.

8. A syringe containing 15 mg (2.0 ml) of 0.75% hyperbaric bupivacaine was firmly attached to the needle. Aspiration of CSF and visualization of a characteristic swirl in the syringe confirmed placement of the needle in the subarachnoid space. The anesthetic was injected over a five second time frame followed by reaspiration and injection of 0.5 ml of CSF to reconfirm placement.

9. The introducer, needle and syringe were removed as a unit and pressure was applied to the injection site. The subject was assisted to the supine position and given instructions not to strain, cough, move or assist with repositioning. This was done to prevent the influence of increased intra-abdominal pressure on the cephalad spread of the anesthetic. The subject and bed were not manipulated for 20 minutes in order to minimize the influence of position on the spread of the anesthetic. Hypotension was treated with fluid administration and ephedrine.

10. To observe for early signs of complications of the subarachnoid block, vital signs were monitored continuously and recorded every five minutes and communication with the subject was maintained.

Midazolam is frequently administered for intravenous sedation during therapeutic and diagnostic procedures, as well as regional anesthesia. The recommended dose for

amnestic, sedative, and anxiolytic effects can be achieved in therapeutic dosages of up to 0.1 mg/kg (Reves, Fragen, Vinik, & Greenblatt, 1985). Doses within or above this range may render a patient unconscious, therefore the dose must be individualized and titrated slowly. The investigators of this study used a therapeutic range (0.0 to 0.1 mg/kg) for anxiolysis, which maintained the subject's ability to sense and verbalize a change (sharp versus dull) in the quality of sensation elicited by a 22 gauge needle. Because the amount of midazolam required for anxiolysis varies among individuals, the amount administered was recorded on the data collection tool and analyzed at the conclusion of the study as a possible confounding variable.

#### Study Design

A nonexperimental, prospective, one-group, correlational design was used for this study. The inclusion criteria were carefully selected in order to control for extraneous variables such as obesity, pregnancy, and emergencies.

The consistency and accuracy of the values obtained for patient height, vertebral column length, and level of sensory blockade were established to minimize observer error or bias. Interrater reliability was established among the researchers to ensure consistency in the measurements of patient height (100%) and vertebral column length (95%). The level of sensory blockade using the pinprick method was determined using an independent, blinded observer unaware of the previously measured vertebral column length. Interrater reliability (92%) was also established between the four blinded observers to ensure that dermatome level assessment was consistent among the observers and to exclude the introduction of bias into the study.

### Proposed Data Analysis

The Statistical Package for Social Sciences (SPSS) was used to analyze the data. Descriptive statistics were used to summarize demographic data such as age, gender, height, vertebral column length, ethnicity, and ASA classification. The independent variables, patient height and vertebral column length, as well as the dependent variable, level of sensory blockade, were measured on a continuous scale. Pearson's Product Moment Correlation ( $r$ ) was used to answer the research question in this study: What is the correlation between patient height versus vertebral column length and the dermatomal level of sensory blockade produced using 15 mg of 0.75% hyperbaric bupivacaine.

### Summary

This study used a nonexperimental, prospective, correlational design to determine if using patient height versus the vertebral column length served to more accurately determine the level of sensory blockade achieved during spinal anesthesia. Informed consent was obtained during the preoperative period. All investigators used a standardized technique for subarachnoid block. Based on power analysis (Cohen, 1992), a sample size of 85 subjects was required. Assessment of the level of sensory blockade took place 20 minutes after injection of 15 mg of 0.75% hyperbaric bupivacaine. The findings were analyzed using a Pearson's Product Moment Correlation ( $r$ ) with a level of significance established as  $p \leq 0.05$ .

## CHAPTER IV

### Analysis of Data

This study was conducted to determine the strength of the relationship between patient height versus vertebral column length and the level of sensory blockade produced following subarachnoid administration of 15 mg of 0.75% hyperbaric bupivacaine in selected surgical patients undergoing spinal anesthesia. The study population was composed primarily of young, healthy, active-duty male soldiers undergoing spinal anesthesia for elective surgical procedures at an Army community hospital in Central Texas. The research findings are presented in this chapter.

#### Description of Sample

One hundred and seven patients were solicited to participate in the research. Five patients, who provided no specific reasons for refusal, declined to take part in the study. Of the one hundred and two subjects that were recruited to participate in the study, data collection was terminated on four subjects. Two subjects had failed subarachnoid blocks; one patient required a 22 gauge subarachnoid needle for block placement; and one patient's leg was raised (above the level of the hip) by the surgeon prior to the measurement of the dermatome level. Therefore, the original sample consisted of 98 subjects, 87 men and 11 women.

The researchers intended to accrue patients of both genders. Midway through the data collection period, it became apparent that gender parity would not be attainable due to the nature of the population served and types of surgeries performed. A decision was

made to accrue only male subjects and eliminate women from the study in order to achieve a homogeneous sample. The demographic information concerning the eleven women accrued in the study is presented in Table 1.

Table 1

Demographic Characteristics of the Sample (N = 11; Female Subjects)

	Range	M	SD
Age in years	20-49	29	10
Height (cm)	161-180	169	6
Vertebral column length (cm)	50-65	56	4
Weight (kg)	55-91	68	12
ASA Classification	I: 4 II: 7		

Among the 87 male subjects accrued, data analysis revealed two outliers with regard to patient height. These patients were eliminated from the study in order to create a more homogenous sample. The final sample consisted of 85 male subjects. The demographic characteristics of the sample are summarized in Tables 2 and 3.

Table 2

Demographic Characteristics of the Sample (N = 85; Male Subjects )

	Range	<u>M</u>	<u>SD</u>
Age in years	19-60	34	10
Height (cm)	164-192	178	6
Vertebral column length (cm)	44-69	59	4
Weight (kg)	58-103	81	11

Table 3

Demographic Characteristics of the Sample (N = 85; Male Subjects)

---

ASA Classification                    I: 37 (44 %)

                                          II: 48 (56%)

Surgical Procedure:

Orthopedic                            61 (71.8%)

General Surgery                    19 (22.4%)

Urologic                            5 (5.9%)

Ethnicity:

Caucasian                            56 (65.9%)

African-American                    21 (24.7%)

Hispanic                            8 (9.4%)

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Eighty-three patients required midazolam for anxiolysis. No patients exceeded the determined therapeutic maximum dose of 0.1 mg/kg. Information regarding the administration of midazolam is summarized in Table 4.

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Table 4

Administration of Midazolam (N = 85)

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	Range	<u>M</u>	<u>SD</u>
Total dose (mg)	0 - 5.0	2.0	0.9
Dose in mg/kg	0 - 0.06	0.03	0.01

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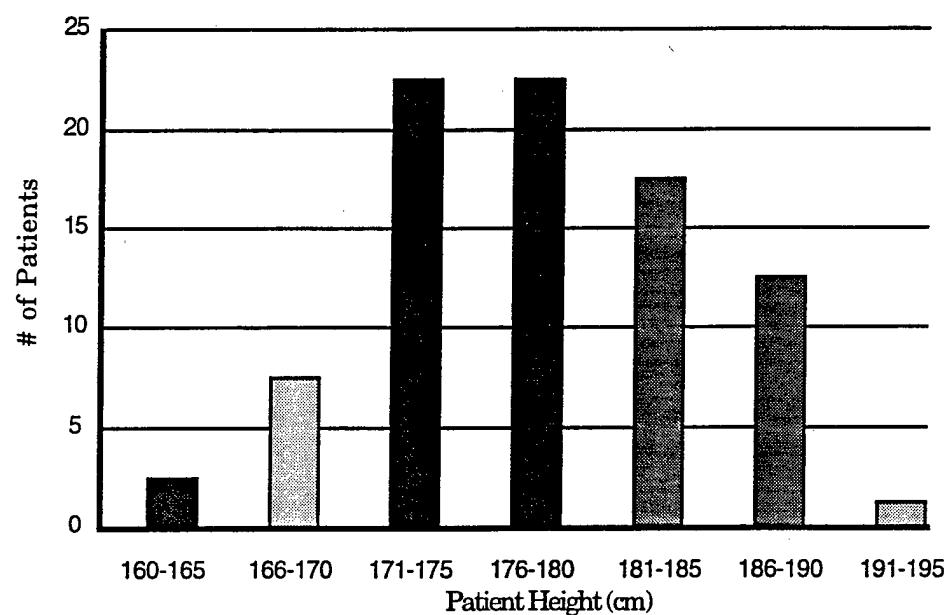
Findings

The purpose of this study was to determine the strength of the relationship between patient height versus vertebral column length and the level of sensory blockade produced following subarachnoid administration of 15 mg of 0.75% hyperbaric bupivacaine. Data analysis demonstrated that ASA I and II male subjects, between the heights of 164 cm (65 in) and 192 cm (76 in), achieved an average level of sensory blockade of T6 (range of T2-12) following a subarachnoid injection of 15 mg of 0.75% hyperbaric bupivacaine.

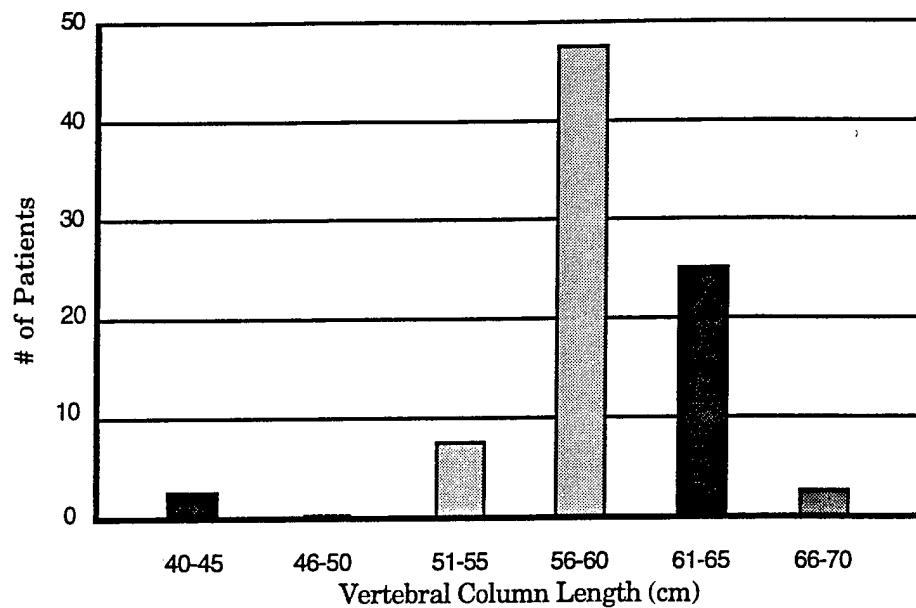
The relationship between vertebral column length and level of sensory blockade as well as patient height and level of sensory blockade was analyzed using Pearson's Product Moment Correlation (r). The Pearson's Product Moment Correlation was selected

because the data met the following assumptions: a normalized distribution (Figures 2 and 3), a representative sample, a linear relationship between X:Y, and homoscedasticity. The study findings demonstrated a weak, albeit statistically significant correlation ( $r = -0.21$ ;  $p = 0.05$ ) between patient height and the level of sensory blockade and no correlation between vertebral column length and level of sensory blockade ( $r = -0.05$ ;  $p = 0.62$ ; ns).

The literature suggested that age and weight (Cameron et al., 1981; Greene; 1985) may exert an influence on the level of sensory blockade. Anxiolytic agents alter a patient's sensorium (Stoelting & Miller, 1994) and thereby may influence the subject's perception of the level of sensory blockade. Therefore, the researchers believed it was important to examine age, weight, and midazolam as potential confounding variables. Partial correlations were used to statistically control for the confounding influence of a third variable upon the independent variables studied. The data concerning age, weight, mg/kg and total dose of midazolam administered were examined through the use of partial correlations. This analysis illustrated that when controlling for weight, there was no correlation ( $r = -0.18$ ;  $p = 0.11$ ) between patient height and dermatome level. Further analysis demonstrated that patient height and dermatome level were weakly correlated when controlling for age ( $r = -0.21$ ;  $p = 0.06$ ), mg/kg dose of midazolam ( $r = -0.22$ ;  $p = 0.04$ ), and total dose of midazolam ( $r = -0.23$ ;  $p = 0.03$ ). When controlling for the total dose of midazolam administered, the correlation between patient height and dermatome level was slightly stronger ( $r = -0.23$  versus  $r = -0.21$ ). Additional analysis demonstrated no correlation between vertebral column length and dermatome level when



**Figure 2.** Distribution of patient height.



**Figure 3.** Distribution of vertebral column length.

controlling for age ( $r = -0.05$ ;  $p = 0.62$ ), weight ( $r = -0.03$ ,  $p = 0.76$ ), mg/kg dose of midazolam ( $r = -0.08$ ;  $p = 0.46$ ) and total dose of midazolam ( $r = -0.08$ ;  $p = 0.47$ ).

There was a moderate, statistically significant correlation between patient height and vertebral column length when controlling for age ( $r = 0.63$ ,  $p = 0.00$ ), weight ( $r = 0.61$ ,  $p = 0.00$ ), mg/kg dose of midazolam ( $r = 0.63$ ,  $p = 0.00$ ) and total dose of midazolam ( $r = 0.61$ ,  $p = 0.00$ ).

#### Summary

This study was conducted to determine the strength of the relationship between patient height versus vertebral column length and the level of sensory blockade produced following subarachnoid administration of 15 mg of 0.75% hyperbaric bupivacaine in selected surgical patients undergoing spinal anesthesia. When controlling for the total dose of midazolam administered, the correlation between patient height and the level of sensory blockade was strengthened. In this sample, there was a moderate, statistically significant correlation between patient height and vertebral column length when controlling for age, height, mg/kg and total dose of midazolam. Study findings demonstrated that there was a weak, albeit statistically significant correlation between patient height and level of sensory blockade and no correlation between vertebral column length and level of sensory blockade.

## CHAPTER V

### Discussion, Conclusions, Implications, and Recommendations

The purpose of this study was to determine the strength of the relationship between patient height versus vertebral column length and the level of sensory blockade produced following subarachnoid administration of 15 mg of 0.75% hyperbaric bupivacaine in selected surgical patients undergoing spinal anesthesia. A discussion of the conceptual framework, a comparison of the findings with previous research, an identification of strengths and weaknesses, and a review of the conclusions will be presented. Clinical implications and suggestions for future research will also be provided.

#### Discussion

The nine factors identified in the conceptual framework (see Figure 1) were grouped into four categories: patient characteristics, CSF characteristics, anesthetic solution characteristics, and technique. These factors are known to influence the distribution of local anesthetics in the subarachnoid space and the resultant level of sensory blockade achieved. This research focused on patient characteristics, with vertebral column length and patient height as the independent variables.

The review of literature guided the selection of variables under study. In addition, the conceptual framework helped to identify potential confounding variables. Methods employed included strict sample inclusion and exclusion criteria, and the use of a standardized solution and measurement technique for patient height, vertebral column length, and level of sensory blockade achieved. In addition, interrater reliability was

established among the blinded observers (92%). A Pearson's Product Moment Correlation was used to analyze the data.

The research question under investigation was: What is the correlation between patient height versus the length of the vertebral column and the dermatomal level of subarachnoid sensory blockade produced when using 15 mg of 0.75% hyperbaric bupivacaine? There was a weak, negative correlation between patient height and the level of sensory blockade achieved ( $r = -0.21$ ,  $p = 0.05$ ). However, there was no correlation between vertebral column length and level of sensory blockade ( $r = -0.05$ ,  $p = 0.62$ ). When controlling for weight, there was no correlation ( $r = -0.18$ ;  $p = 0.11$ ) between patient height and dermatome level. Furthermore, there was a moderate, statistically significant correlation between patient height and vertebral column length when controlling for age ( $r = 0.63$ ,  $p = 0.00$ ), weight ( $r = 0.61$ ,  $p = 0.00$ ), mg/kg dose of midazolam ( $r = 0.63$ ,  $p = 0.00$ ) and total dose of midazolam ( $r = 0.61$ ,  $p = 0.00$ ). An additional finding was that subjects between the heights of 164 cm (65 in) and 192 cm (76 in) achieved an average level of sensory blockade of T6.

The findings of this study are consistent with that of Attygalle (1985) who found a weak, negative correlation ( $r = -0.2$ ,  $p < 0.001$ ) between patient height and dermatome level when using 10 mg of 0.5% hyperbaric cinchocaine. Additionally, Huffnagle et al. (1994) found a weak correlation ( $r = 0.38$ ,  $p < 0.05$ ) between height and subarachnoid spread in a sample of 44 postpartum patients. In contrast, Hartwell et al. (1991) found a weak, nonsignificant correlation ( $r = 0.22$ ,  $p = 0.13$ ) between patient height and the level of sensory blockade. Also, Norris (1988) reported a weak, nonsignificant correlation

( $r = 0.21$ ,  $p = 0.15$ ) between patient height and level of sensory blockade.

The findings of this study are consistent with Huffnagle et al. (1994) and Norris (1990) whose results were the same in that there was no correlation between vertebral column length and level of sensory blockade ( $r = 0.1673$ ,  $p > 0.05$  and  $r = 0.1673$ ,  $p > 0.05$  respectively). In contrast, Hartwell et al. (1991) reported a weak, statistically significant correlation ( $r = 0.32$ ,  $p = 0.025$ ) between vertebral column length and level of sensory blockade.

The literature led the investigators to believe that weight, age, and midazolam (Cameron et al., 1981; Greene, 1985; Stoelting & Miller, 1994) may influence the relationship between patient height versus vertebral column length and the level of sensory blockade. The literature suggests that weight, except in extreme circumstances (BMI  $> 35$ ), does not influence the level of sensory blockade. A partial correlation was performed, which confirmed that weight did not influence the relationship between patient height and the level of sensory blockade achieved ( $r = -0.18$ ,  $p = 0.11$ ).

Discrepancies exist concerning the effect of age on the level of sensory blockade. Some studies found increased patient age to be associated with statistically significant higher levels of sensory blockade (Cameron et al., 1981; Pitkanen et al., 1984). In this study, as in other studies (Norris, 1990; Tuominen et al., 1987; Veering et al., 1987) the relationship between age and the height of spinal anesthesia was not found to be clinically significant. This study controlled for age by selecting patients who met the inclusion criteria (18-60 years old). Future research should not discount age as a possible variable having an influence on the level of sensory blockade.

In the review of literature, it was apparent that anxiolytic agents were frequently administered and not accounted for as possible confounding variables. The investigators of this study recognized the administration of midazolam as a possible confounding variable. The research findings clearly demonstrated that midazolam was a confounding variable. The partial correlation between patient height and dermatome level became slightly stronger ( $r = -0.22, p = 0.04$ ) when controlling for the mg/kg dose of midazolam administered. The partial correlation between patient height and dermatome level became even stronger ( $r = -0.23, p = 0.03$ ) when controlling for the total dose of midazolam administered. This analysis demonstrated that the total dose of midazolam exerted the greatest influence on the relationship between patient height and level of sensory blockade.

The average level of sensory blockade in this study was T6. This supported the findings of Hartwell et al. (1991) in that the mean level of sensory blockade produced was T6. In contrast, Norris (1988) reported an average dermatome level of T3.

It is important to note that three clinically important differences exist between the previous studies and this investigation. These three differences concern characteristics of the sample, anesthetic solution administered, and patient position. The most important difference noted was that Hartwell et al. (1991), Huffnagle et al. (1994) and Norris (1990) used parturients and/or postpartum patients in their sample. The physical characteristics of the parturient may influence the level of sensory blockade achieved during spinal anesthesia. These changes include an exaggerated lumbar lordosis, diminished thoracic kyphosis, epidural venous engorgement, and increased sensitivity to local anesthetics. These changes may extend six weeks into the postpartum period.

It is difficult to compare the findings of this study to previous studies in that the dosage and type of local anesthetic administered differed. Hartwell et al. (1991) administered 12 mg of 0.75% hyperbaric bupivacaine whereas Huffnagle et al. (1994) administered 75 mg of 5% hyperbaric lidocaine. Norris (1990) administered 15 mg of 0.75% hyperbaric bupivacaine to his patients, which is similar to this study.

The local anesthetic in this study was administered with subjects in the sitting position. In contrast, Hartwell et al. (1991) administered the anesthetic with subjects in the right lateral decubitus position. This change in patient position may be a contributing factor to the difference in the findings between the two studies. Because differences exist between the previous studies and this study concerning the characteristics of the sample, anesthetic solution, and patient position, the findings from previous studies and this study are difficult to generalize.

The selection of variables listed in the conceptual framework (see Figure 1) was guided by the review of the literature. A revised conceptual framework (see Figure 4) reflects the research findings of this study. Since there was no correlation between vertebral column length and the level of sensory blockade, vertebral column length was eliminated from the conceptual framework. The findings clearly demonstrated that midazolam was a confounding variable. The investigators believed that it would be unethical to control for the confounding effects of midazolam by eliminating its use. Therefore, the researchers revised the conceptual framework and added midazolam as a possible confounding variable. This illustrates that anesthesia providers need to consider the effects of

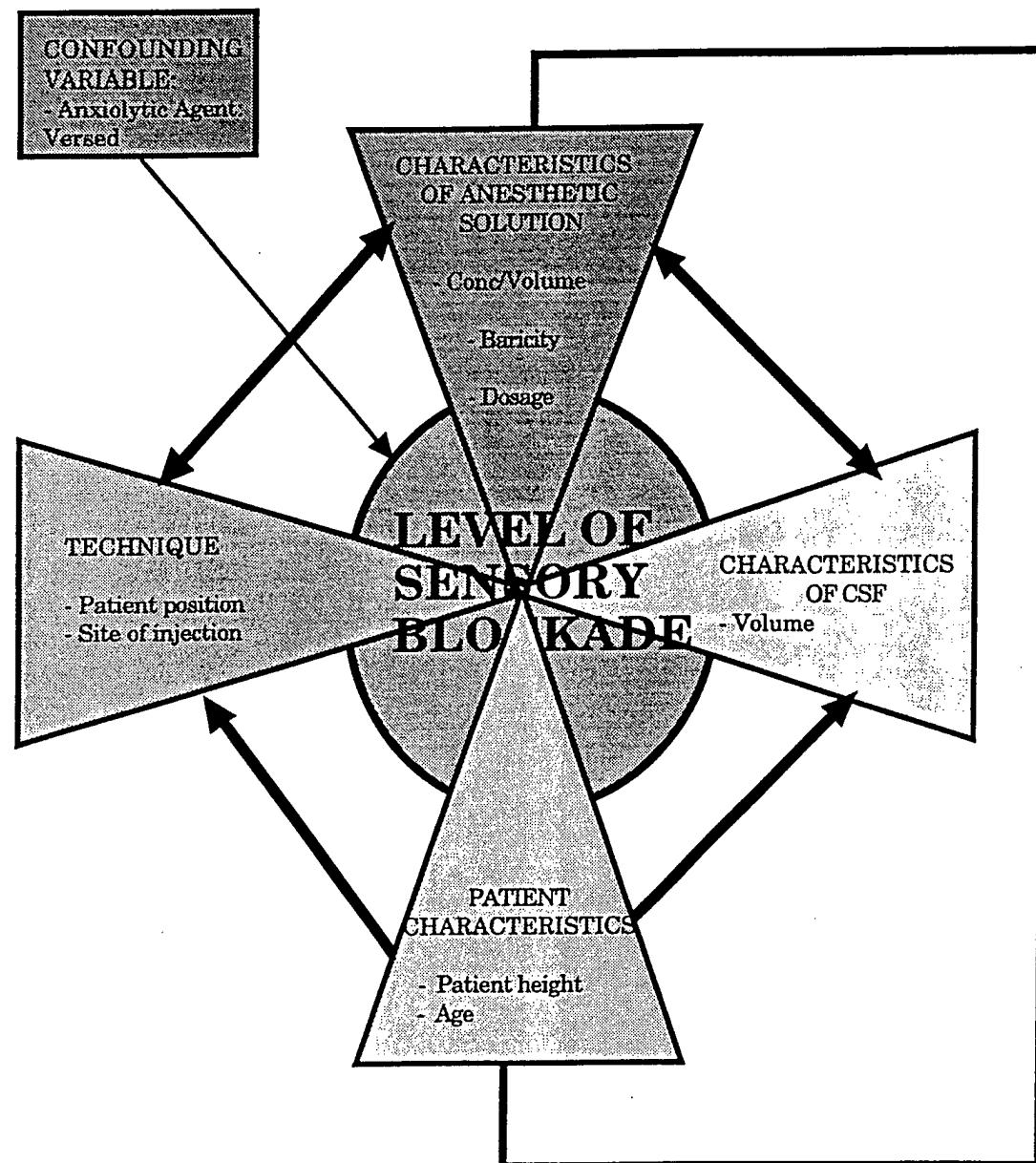


Figure 4. Factors influencing distribution of anesthetic within the subarachnoid space.

midazolam when assessing the level of sensory blockade. The revised conceptual framework should be used to guide future research replicating this study.

### Strengths of the Study

Strengths of this study included: the use of power analysis to determine sample size, a homogeneous sample, a normalized distribution, control and examination of confounding variables, use of a standardized technique, and interrater reliability. According to Cohen (1992), this study required a sample size of 85 subjects to provide the researchers the statistical power to detect an effect between the variables investigated. Due to the homogeneity of the final sample, a normal distribution with low variability was obtained.

The methodology of the study provided a high level of control concerning the potential effects of confounding variables on the dependent variable, level of sensory blockade. Spinal anesthesia was performed by four researchers with the same skill level and experience. All researchers used a specific, standardized protocol for the administration of the subarachnoid block to minimize differences in technique. In addition, interrater reliability for subject height (100%) and vertebral column length measurements (95%) was established among the researchers.

The determination of the level of sensory blockade 20 minutes after the administration of 15 mg of 0.75% hyperbaric bupivacaine was restricted to four independent, blinded observers unaware of the previously measured vertebral column length and height. This ensured that the proper dermatome level was being recorded and excluded bias between the researchers and the blinded observers. Interrater reliability (92%) was established among the blinded observers with regard to measurement of

dermatome level.

The effect of midazolam on the subject's perception of the level of sensory blockade was recognized by the researchers as a possible confounding variable. Therefore, the amount of midazolam administered for anxiolysis was limited to a dosage of up to 0.1 mg/kg and documented. Both the total and mg/kg dose of midazolam were analyzed using partial correlations.

#### Weaknesses of the Study

The sample was derived from a military population consisting predominantly of young, healthy male patients. Initially, no attempt was made to exclude women from this study. However, due to time constraints, the population served, and the surgical procedures performed, it was obvious that gender parity could not be established. A decision was made to exclude women from the study and continue to accrue only male subjects. Therefore, the research findings can only be generalized to patients with characteristics similar to those who participated in this study.

Eighty-three subjects who presented for surgery required the administration of midazolam for anxiolysis. The amount of midazolam required varied among subjects. Therefore, the dose of midazolam administered was titrated to meet individual needs and could not be standardized. While it was a strength that the researchers controlled for the total dose of midazolam, midazolam was determined to be a confounding variable.

In view of the fact that subarachnoid blocks were administered to subjects using a fixed dose of local anesthetic in the sitting position, the focus of this study was limited. Therefore, the results of this study can only be generalized to patients in which a

comparable anesthetic solution and technique is used.

### Conclusions

1. The findings of this study clearly support that patient height rather than vertebral column length can be used to determine anesthetic dosage for subarachnoid blockade. There was a weak, albeit statistically significant correlation between patient height and the level of sensory blockade.
2. There was no clinically or statistically significant relationship between vertebral column length and the level of sensory blockade when 15 mg of 0.75% hyperbaric bupivacaine was used.
3. When controlling for the total dose of midazolam administered, the correlation between patient height and the level of sensory blockade was strengthened.
4. The mean level of sensory blockade in this population was T6 with a standard deviation of two dermatomes.

### Clinical Implications for Nursing Practice

The findings from this study have numerous important clinical implications both for the anesthesia provider and patients in civilian and military health care settings. Although the sample in this study was drawn from a military population, the results may be generalized to other clinical settings that serve young, healthy men. Examples of these settings are same-day surgical and sports medicine centers.

Traditionally, anesthesia providers have used patient height to estimate the dose of local anesthetic for subarachnoid blockade during surgery. When comparing the time required to measure patient height versus vertebral column length, it took an average of

one minute and five minutes respectively. Since patient height was correlated with dermatome level and vertebral column length was not, it is clearly more efficient for the anesthetist to measure patient height. Because this study provides the scientific data to support traditional practice, anesthesia providers may continue to use patient height to estimate required anesthetic dosages for subarachnoid blockade.

When examining for confounding variables, the total dose of midazolam administered intravenously for anxiolysis influenced the relationship between patient height and the level of sensory blockade more than the mg/kg dose. Therefore, anesthesia providers need to recognize the effect of the total dose of midazolam when assessing the level of sensory blockade.

An additional finding was that subjects between the heights of 164 cm (65 in) and 192 cm (76 in) achieved an average level of sensory blockade of T6. Clinically, this offers the anesthetist a reliable estimate of sensory blockade when using 15 mg of hyperbaric bupivacaine for spinal anesthesia. This ability to anticipate the level of sensory blockade translates into cost-effective use of anesthesia and operating room resources. Surgical delays and extended recovery room stays due to complications related to inadequate or excessively high spinal blockade can be reduced. Furthermore, adequate sensory blockade during spinal anesthesia offers the patient a more pleasant surgical experience with some sense of control, a diminished pain response, and an earlier hospital discharge.

The findings of this study have tremendous implications for the military anesthetist during periods of deployment (national disasters, peacekeeping/humanitarian missions, and low-intensity conflicts) when spinal anesthesia is appropriate. Resources and personnel

are severely limited in the field environment. As stated previously, the ability to estimate the level of sensory blockade during spinal anesthesia can limit complications associated with an inadequate or excessively high block. These complications impose a great burden on the surgical unit in the immediate postanesthesia recovery period and sharply decrease mission effectiveness. When patients require an extended recovery period due to complications from an inadequate or excessively high block, scarce resources such as time, supplies and personnel are exhausted. This prevents the flow of casualties to the next echelon of care and reduces the unit's ability to accept additional casualties.

The sample in this study closely resembles the majority of casualties encountered by the military anesthetist during times of deployment. Therefore, the findings facilitate the anesthetist in more accurately determining the anesthesia resources needed for unit deployment. Also, this study describes an anesthetic plan that is adequate for the majority of casualties presenting for surgical procedures where spinal anesthesia is appropriate. The generalizability of the findings for this patient population offers the anesthetist a quick and easy estimation of local anesthetic based on height. It also provides the anesthetist with the option of a quick and reliable spinal anesthesia plan using 15 mg of 0.75% hyperbaric bupivacaine for a T6 blockade.

Soldier readiness can be enhanced when complications due to inadequate or excessively high spinal anesthesia are decreased due to a more reliable estimation of sensory blockade. When appropriate management of a spinal anesthetic is provided for a surgical procedure, a soldier's risk of loss of life due to an anesthetic mishap is reduced. The soldier is returned to duty or is evacuated sooner with less complication related to the

spinal anesthetic. Whether in peace or in conflict, this implication is beneficial to the readiness of the country's fighting force.

#### Recommendations for Future Research

Further research evaluating heterogeneous and homogeneous groups consisting of both male and female subjects using 15 mg of 0.75% hyperbaric bupivacaine should be conducted to determine the relationship between patient height, vertebral column length, and the level of sensory blockade. Additionally, this research should be replicated using homogeneous groups such as parturients and geriatric subjects of both genders. Ideally, replication of this study should be conducted using three groups of patients in the sitting, left lateral, and right lateral decubitus position. This would allow the researcher to make comparisons across groups. This study also could be used to develop new studies examining a variety of local anesthetics, dosages, and patient heights.

#### Summary

This study was conducted to determine the strength of the relationship between patient height versus vertebral column length and the level of sensory blockade produced following administration of 15 mg of 0.75% hyperbaric bupivacaine in selected surgical patients undergoing spinal anesthesia. Study findings demonstrated that there was no correlation between vertebral column length and level of sensory blockade, and a weak correlation between patient height and level of sensory blockade. When comparing the time required to measure patient height versus vertebral column length, it took an average of one minute versus five minutes, respectively. Based on this finding, it is clearly more efficient to use patient height to estimate anesthetic dosages for subarachnoid blockade.

These findings also support traditional practice of estimating dosages based on patient height.

The patient's perception of the level of sensory blockade may be diminished with the administration of midazolam. When controlling for the total dose of midazolam administered, the correlation between patient height and the level of sensory blockade was strengthened. Anesthesia care providers should be aware that the total dose of midazolam exerts a greater impact on the patient's perception of the level of sensory blockade than the mg/kg dosage.

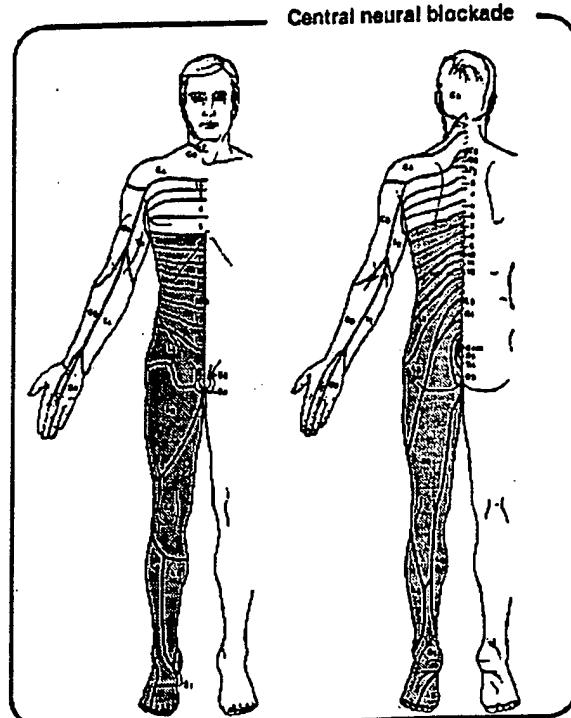
The research findings demonstrated that ASA I and II male subjects, between the heights of 164 cm (65 in) and 192 cm (76 in), achieved an average level of sensory blockade of T6 when 15 mg of 0.75% hyperbaric bupivacaine was administered. The generalizability of this finding offers the anesthetist a quick and reliable anesthesia plan for patients within this height range. The ability to anticipate the level of sensory blockade benefits both the patient and organization by limiting the complications associated with an inadequate or excessively high spinal blockade.

The ability to estimate the level of sensory blockade has significant implications for the military. When perioperative complications are decreased, soldier readiness is enhanced, and the risk of loss of life due to an anesthetic mishap is avoided. The soldier is returned to duty or is able to be evacuated sooner.

## APPENDIX A

### Data Collection Tool

A DATA COLLECTION TOOL  
FOR THE USA-UTHHSC PROGRAM IN ANESTHESIA NURSING STUDY

DATE: / /	DERMATOME LEVEL/20:
PATIENT'S HOSPITAL #:	INJECTION SITE:
AGE:	ASA STATUS:
M/F: ETHNICITY:	SEDATION:
HEIGHT: (cm) WEIGHT: (kg)	DERMATOME CHART:
VERTEBRAL COLUMN LENGTH:	
SURGICAL PROCEDURE:	
	

## APPENDIX B

### Informed Consent Form

**VOLUNTEER AGREEMENT AFFIDAVIT**

For use of this form, see AR 70-25; the proponent agency is OTSG

**PRIVACY ACT OF 1974****Authority:**

10 USC 3013, 44 USC 1101, and 10 USC 1071-1087.

**Principle Purpose:** To document voluntary participation in the Clinical Investigation and Research Program. SSN and home address will be used for identification and locating purposes.**Routine Uses:** The SSN and home address will be used for identification and locating purposes. Information derived from the study will be used to document the study, implementation of medical programs, adjudication of claims and for the mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State and local agencies.**Disclosure:** The furnishing of your SSN and home address is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in the investigational study.**PART A(1) - VOLUNTEER AFFIDAVIT**

Volunteer Subjects in Approved Department of the Army Research Studies

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized all necessary medical care for injury or disease which is the proximate result of their participation in such studies.

I, \_\_\_\_\_, SSN \_\_\_\_\_, having full capacity to consent and having attained my \_\_\_\_\_ birthday, do hereby volunteer/give consent as legal representative for \_\_\_\_\_ to participate in \_\_\_\_\_

\* Influence of Patient Height Versus Vertebral Column Length on the Spread of Hyperbaric 0.75% Bupivacaine  
(Research Study)

under the direction of Bonnie Bequette RN, BSN (CPT, Army Nurse Corps)  
conducted at Darnall Army Community Hospital  
(Name of Institution)

The implications of my voluntary participation/consent as legal representative; duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by:

Bonnie Bequette RN, BSN (CPT, Army Nurse Corps)

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights/the rights of the person I represent on study-related injury, I may contact:

Center Judge Advocate at Darnall Army Community Hospital (817)288-6307 (DSN 738)  
or the Clinical Research Protocol Coordinator  
at Brooke Army Medical Center, FSHTX (210) 916-9495  
(Name, Address and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my consent and withdraw/have the person I represent withdrawn from the study without further penalty or loss of benefits; however, the person I represent may be required (military volunteer) or requested (civilian volunteer) to undergo certain examinations if, in the opinion of the attending physician, such examinations are necessary for my/the person I represent's health and well-being. My/the person I represent's refusal to participate will involve no penalty or loss of benefits to which I am/the person I represent is otherwise entitled.

**PART A(2) - ASSENT VOLUNTEER AFFIDAVIT (MINOR CHILD)**

I, \_\_\_\_\_, SSN \_\_\_\_\_, having full capacity to consent and having attained my \_\_\_\_\_ birthday, do hereby volunteer for \_\_\_\_\_ to participate in \_\_\_\_\_

(Research Study)

under the direction of \_\_\_\_\_  
conducted at \_\_\_\_\_  
(Name of Institution)

(Continue on Reverse)

**PART A(2) - ASSENT VOLUNTEER AFFIDAVIT (MINOR CHILD) (Cont'd)**

The implications of my voluntary participation; the nature, duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconvenience and hazards that may reasonably be expected have been explained to me by

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights I may contact

at \_\_\_\_\_  
(Name, Address and Phone Number of Hospital (Include Area Code)

I understand that I may at any time during the course of this study revoke my assent and withdraw from the study without further penalty or loss of benefits; however, I may be requested to undergo certain examination if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

**PART B - TO BE COMPLETED BY INVESTIGATOR**

INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT: (Provide a detailed explanation in accordance with Appendix E, AR 40-38 or AR 70-25).

**TO: PARTICIPANTS IN THIS STUDY**

\* You are invited to participate in a research study of 85 patients involving spinal anesthesia. The purpose of this study is to determine if (a) patient height or (b) length of the spinal (vertebral) column is a better indicator of the level of pain (sensory) block achieved following spinal anesthetic administration. If there is a difference, this may allow anesthesia providers to more accurately judge the level of pain(sensation) loss for patients. We will insure that you will be provided with optimal and safe pain control (blockade) required for your surgery.

This study is being conducted by graduate students in the U.S. Army Nurse Anesthesia Course under the supervision of a faculty member. You have been identified as a potential participant in this study because a spinal is an appropriate anesthesia technique for your proposed surgical procedure. Your anesthesia provider will discuss all anesthesia options with you during your preanesthetic interview.

(see attached page)

I do  do not  (check one & initial) consent to the inclusion of this form in my outpatient medical treatment record.

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (if volunteer is a minor)
------------------------	------	----------------------------------------------------------

PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS	
	SIGNATURE OF WITNESS	DATE

If you decide to participate in this study, the amount of time you will spend in surgery will not be affected. However, we will be asking for an additional 10 minutes of your time during the pre-surgery interview to sign the consent form, answer personal history questions, and have your back measured. We encourage you to ask questions about the study at any time.

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On the day of your preoperative interview, a measurement of your height and back will be taken. When you are brought into the operating room you will be asked to sit at the edge of the operating bed. Your back will be washed with a special antiseptic solution. A small amount of numbing medicine will be injected into your back. The Whitacre spinal needle will then be inserted into your spinal canal and the anesthetic will be injected. After the needle is removed, you will be helped onto your back to lie flat on the operating bed. You will be closely monitored throughout your entire surgery. In this study, we will use routine information (level of blockade) that we normally collect during the first 20 minutes of surgery. Any patient that coughs, sneezes or bears down (strains) within the first 20 minutes after receiving the anesthetic will be removed from the study because such actions can change the research situation we are trying to evaluate, although such actions will not affect your surgery in any way.

**Risks:**

The drug being used in this study is bupivacaine, which is approved by the Federal Drug Administration, and is frequently used to achieve blockade of pain (anesthesia). This ensures that you will not feel the sensation of pain during your surgery. You will not be exposed to any risks or discomfort other than those that are normally related to spinal anesthesia. These include, but are not limited to, postoperative headache, lower back pain, infection at the injection site, nausea and vomiting and urinary retention. You will be counseled about these risks by an anesthesia provider during the preanesthetic interview. If a complication does occur you will be carefully treated. In the event of physical injury resulting from the surgery, the extent of medical care provided will be within the scope authorized by the Department of Defense. Necessary medical care does not include domiciliary (home or nursing home) care.

**Benefits:**

You may not benefit personally from this study other than to know that the information we gather may help future patients.

You are free to end your participation in this study at any time by telling the researcher. Your decision whether or not to participate or withdraw from the study will not affect your present or future care while you are at Darnall Army Community Hospital. If at any time we think that it is not in your best interest to continue participation in this study, you may be removed from the study without your consent.

Participants are expected to have questions and are encouraged to ask them at any time. Please contact CPT Bonnie Bequette by calling the Department of Anesthesia Services at Darnall Army Community Hospital at (817) 288-8570 or the USA/UTHHSC Program in Anesthesia Nursing, Phase II office at (817) 288-8705. If you have any questions about the ethical, legal or social aspects of this study, the review by the BAMC and University of Texas Institutional Review Boards, or questions that you would like to discuss with someone other than CPT Bequette, you may contact the Clinical Investigation Protocol Coordinator, Brooke Army Medical Center, at (210) 916-9495. The results of this study will be provided to you upon request. This research study will take approximately 9 months to complete.

The information you provide in this study will remain strictly confidential and will not be disclosed to anyone outside the research team. The information gained from your participation in this study may be published in medical literature, discussed for educational purposes and used generally to further medical science. By participating in this research study, you will not be personally identified. All information will be presented as grouped data. Your records may be reviewed by BAMC Institutional Review Board and other regulatory agencies.

A copy of this form will be given to you. Thank you for your participation!!

\*\*\*\*\*  
I have read the previous explanation and agree to participate in the investigational study described.

\_\_\_\_\_  
Volunteer's Initials/Date

\_\_\_\_\_  
Witness's Initials/Date

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### Vita

Bonnie D. Harvey Bequette was born in Anaheim, California on November 10, 1951, the daughter of Earl Joseph Harvey and Dorothy Jane Park. She graduated from Apple Valley High School, Apple Valley California in 1970. Her daughter, Casey, was born in 1971 and her son, Jesse, was born in 1978.

She received the degree of Bachelor of Science in Nursing from the University of Utah in June 1984. In 1988, she received a direct commission into the U.S. Army Nurse Corps and spent the following three years assigned to the 15th Evacuation Hospital, Fort Polk, Louisiana. In 1991, after serving in Operation Desert Shield/Desert Storm, she was assigned to Brooke Army Medical Center where she served as a staff nurse and later head nurse of the Cardiology Ward. In October, 1994 she entered the United States Army/University of Texas-Houston Health Science Center Program in Anesthesia Nursing.

In 1993, she married Lieutenant Glen Raymond Porter, MSC, United States Navy, of Lucedale, Mississippi. She has a step-daughter, Sydney, born in December 1985 and a granddaughter, Danielle, born in November of 1995 to Casey and Jeffrey Williams.

**Vita**

Sandra Sue Ruby Bruner was born in Fort Bragg, North Carolina on August 15, 1964, the daughter of Charles Alfred Ruby and Yong Suk Ruby. After completing her work at Fort Knox High School, Fort Knox, Kentucky, in 1982, she entered Wheaton College in Wheaton, Illinois. She entered Rush University, Chicago, Illinois and received the degree of Bachelor of Science in Nursing in June, 1987. She received the degree of Bachelor of Science in August, 1987 from Wheaton College. She was commissioned in the U.S. Army Nurse Corps and is currently on active duty. She received the Master of Science degree in Human Resource Management and Development from Chapman University in February 1992. In October, 1994, she entered the U.S. Army/University of Texas Houston Health Science Center Program in Anesthesia Nursing. In 1987, she married Scott Francis Bruner. She has one daughter, Katherine Megan Bruner born in 1991.

**Vita**

**Sheila Yvette Jones** was born in Kansas City, Missouri on August 2, 1965, the daughter of **Onnie David Washington** and **Janie Augusta Washington**. After graduation from Ruskin High School, Kansas City, Missouri in 1983, she attended William Jewell College in Liberty, Missouri. In May, 1987 she received a Bachelor of Science in Nursing from William Jewell College. Upon graduation she received a direct commission in the United States Army Nurse Corps. She has served on active duty in many capacities to include staff nurse positions in neonatal intensive care, pediatric, and medical-surgical units. She has also served as head nurse of a newborn nursery and a postanesthesia care unit. She was accepted in to the United States Army/ University of Texas Houston Health Science Center Program in Anesthesia Nursing in October, 1994.

### Vita

Kimberly J. Bjornstad Kurtz was born in Viroqua, Wisconsin on May 31, 1965, the daughter of Garrett Howard Bjornstad and Donna Jane Bjornstad. After completing her work at Westby High School, Westby, Wisconsin, in May 1983, she entered the nursing program at Viterbo College, LaCrosse, Wisconsin. After her sophomore year, she accepted an ROTC scholarship from the University of LaCrosse, Wisconsin. She graduated from Viterbo College with a Bachelor of Science in Nursing, and from the University of LaCrosse as a Distinguished Military Graduate and a Commissioned Officer in the United States Army Nurse Corps. During the following year, she was employed as a clinical staff nurse at William Beaumont Army Medical Center, Fort Bliss, Texas. In 1988, she attended the Perioperative Nurse Course at Fort Lewis, Washington. She served as an operating room nurse at Evans Army Community Hospital, Fort Carson, Colorado for two years. During that time, she was deployed to Saudi Arabia with the 10th Mobile Army Support Hospital in support of Operation Desert Shield/Storm. Upon her return, she married Anthony Michael Kurtz. She was then assigned as an operating room nurse at Blanchfield Army Community Hospital, Fort Campbell, Kentucky for three years. She was again deployed, this time to Somalia with the 86th Evacuation Hospital in support of Operation Restore Hope. Upon her return, she was accepted into the United States Army/University of Texas Houston Health Science Center Program in Anesthesia Nursing in October, 1994.